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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,745	02/04/2004	Anandi Krishnan	12698/46001	5679
26646 7590 04/06/2007 KENYON & KENYON LLP ONE BROADWAY NEW YORK, NY 10004			EXAMINER CHOI, FRANK I	
			ART UNIT	PAPER NUMBER
			1616	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/06/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/772,745

Applicant(s)

KRISHNAN ET AL.

Examiner

Frank I. Choi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over deVries (US Pat. 6,521,247) in view of Siebert et al. (US Pat. 6,368,625).

DeVries discloses a tablet containing iron, in the form of carbonyl iron, folic acid and vitamin B12 for treatment of anemia (Column 3, lines 20-68, column 4, lines 24-34, column 7, lines 8-24). It is disclosed that the active ingredients are mixed with one or more excipients and optional coated with one or more coats, and that the process includes granulation (Column 5, lines 55-68, Column 6, lines 1-4, Column 10, lines 1-15). It is disclosed that the tablet can contain sorbitol as a sweetening agent and tablet diluent (Column 21, lines 16-24, 39-48). It is disclosed that polyethylene oxide is suitable for use as a binder (Column 19, lines 6-20). It is disclosed that the tablet can include cross-linked PV and sodium starch glycolate to aid in the dissolution or disintegration of the iron supplements and other ingredients (Column 19, lines 50-58). It is disclosed that the tablet can contain a lubricant (column 22, lines 13-20).

Siebert et al. disclose an orally disintegratable tablet containing minerals, such as iron, and vitamins, such as folic and vitamin B 12, sorbitol, cross-linked PVP, sodium starch glycolate, effervescent couple, such as a carbonate source and a mouth feel enhancer such as carbolpol (Column 5, lines 33-68. columns 6-8, Column 9, lines 1-15).

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The prior art discloses a tablet containing iron, in the form of carbonyl iron, folic acid and vitamin B12 for the treatment of anemia. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the combination of carbonyl iron with carrier, wetting agent, viscolyzing agent, gas generating agent and mucoadhesive agent and method by mixing and granulating the ingredients forming into a pharmaceutical dosage form. However, the prior art amply suggests the same as the prior art discloses the formation of tablets containing lubricants, coating layers, sorbitol as a diluent, polyethylene oxide as a binder, cross linked PVP and effervescent carbonates as a disintegrating agents and carbolpol to enhance mouth feel, the formation of orally disintegrating tablets and mixing and granulation of the ingredients and compression to form the tablet. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the combination would be suitable for the formation of orally disintegrating tablets having a good mouth feel.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

### ***Conclusion***

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

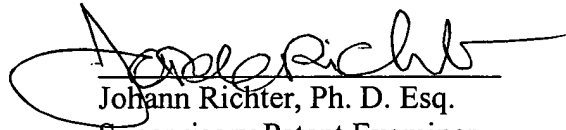
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Dr. Johann Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi  
Patent Examiner  
Technology Center 1600  
April 2, 2007



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